JUN 2 5 2004

510(k) Summary of Safety and Effectiveness

K041017

Submitter:

- SPSmedical Supply Corp.
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- Establishment FDA Registration No.: 1319130
- Date Summary was prepared March 15, 2004
- Gary J. Socola
  Printed name of person submitting for 510(k)
- Gary J. Socola
  Signature of person submitting for 510(k)
- Director of Quality Assurance
  Title of person submitting for 510(k)

Device Name and Classification

Trade Name:	SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets
Classification Name:	Physical/Chemical Sterilization Process Indicator
Common Name:	Bowie Dick Test Pack and Indicator Sheets
Device Classification:	General Hospital - Class II, Regulation Number 880.2800(b)
Product Code:	80JOJ
Predicate Device:	3M Comply Bowie & Dick Test Pack 510(k) no. 841168

Device Description

The SPSmedical AirView™ Bowie Dick Test Pack (BD Test Pack) is a disposable device which is intended for use as a replacement for the ANSI/AMMI ST46:2002 BD Test Pack. The SPSmedical AirView™ Bowie Dick Indicator Sheets are designed to be used within the ANSI/AMMI ST46:2002 BD Test Pack.

Intended Use

The SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick indicator sheets are designed to detect the presence of residual air in pre-vacuum steam sterilizers operating at 134°C. The BD test pack and indicator sheets are reliable tools used for the monitoring of air removal in steam pre-vacuum processes and provides a visual indication if residual air was left in the chamber during sterilization. Its internal indicator sheet changes to a uniform DARK BROWN/BLACK signal color under proper sterilization and air removal conditions. A failure would result in a non-uniform color change on the indicator sheet.

Technical Characteristics

The layers of paper within the SPSmedical AirView™ Bowie Dick Test Pack provide resistance to steam penetration and also trap air between them which is difficult for marginal performing pre-vacuum sterilizers to remove.

Performance Testing

Testing was performed in order to determine the functional equivalency between the SPSmedical Supply Corp's newly developed AirView™ Bowie Dick Test Pack (BD Test Pack) and AirView™ indicator sheets, the 3M Comply Bowie Dick Type Test Pack and the ANSI/AMMI ST46:2002 BD Test Pack. Based on the results of laboratory tests; the SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick indicator sheets are substantially equivalent to the predicate 3M Comply Bowie Dick Type Test Pack and indicator sheets.

Recommended Storage Conditions

Store in a cool, dry place (15-30°C).

Interfering Substances or Conditions

Testing verified that the indicators in their *unprocessed* form are not sensitive to an acidic or basic environment. Testing verified that the indicators in their *processed* form are not sensitive to an acidic or basic environment.

Shelf life

The shelf life of the SPSmedical Bowie-Dick Test Pack and indicator sheets shall be 3 years from the date of manufacture, when stored in a cool, dry place (15-30°C).

Biocompatibility

A risk analysis was performed concerning the materials used in the manufacturing of the AirView™ Bowie Dick Test Pack and AirView™ indicator sheets as well as on any by products created from these materials that may occur during sterilization. Risk analysis concludes that the manufacturing and subsequent use of this product has a low associated risk and that the product is safe for its intended use and handling.

Conclusion

Supportive data has demonstrated that the SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick indicator sheets are equivalent to the predicate device. The SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick indicator sheets raise no issues related to safety or effectiveness and therefore should be allowed for market in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 5 2004

SPSmedical Supply Corporation
C/O Mr. Neil E. Devine
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K041017
Trade/Device Name: SPSmedical AirView™ Bowie Dick Test Pack & AirView™ Bowie Dick Indicator Sheets
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: June 9, 2004
Received: June 10, 2004

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS for USE

510(k) Number (if known): K041017

Device Name: AirView™ Bowie Dick Test Pack & AirView™ Bowie Dick Indicator Sheets

Indications For Use:

The SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick indicator sheets are designed to detect the presence of residual air in pre-vacuum steam sterilizers. When tested in a pre-vacuum sterilizer operating at 134°C the indicator will demonstrate a uniform color change from cream or blue to dark brown/black when proper sterilization conditions have been met and no air is detected. It is designed to be used for daily Bowie Dick testing of steam sterilizers as described in AAMI/ANSI ST-46.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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